

N91-32780

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-K6490865

— 41 —

- Compare prothrombin times, pre-flight, in-flight, and post-flight, on test subjects.
- To determine the most effective positioning of the monitor in order to accurately place a drop of blood on the test cartridge.

MATERIALS:

- Ciba-Corning 512 Coagulation Monitor
- 2 Autolancets (including replacement lancets)
- Nonsterile 2x2 gauze pads
- Alcohol wipes
- PT cartridges (foil wrapped)
- PTT cartridges (foil wrapped)
- Tape
- Permanent markers
- Towels
- Lap board with biohazard box and supply box (velcroed to board)
- Extra battery pack
- Test simulator
- Latex gloves
- Band-aids
- Kimwipes

- 50 microliter capillary tubes with plungers
- Report sheets and clipboard
- Writing pen
- Stopwatch

FLIGHT PERSONNEL:

- | | |
|----------------------|-------|
| 1. Robyn Gocke | MDSSC |
| 2. Chuck Lloyd | NASA |
| 3. Nancy Greenthaner | KRUG |

GROUND SUPPORT:

1. Terry Guess
2. Art Freeman

VIDEO SUPPORT:

Video support and still photos are requested if available on the flight.

PRE-FLIGHT PROCEDURES

1-G Testing of the Ciba-Corning 512 Coagulation Monitor:

Study #1

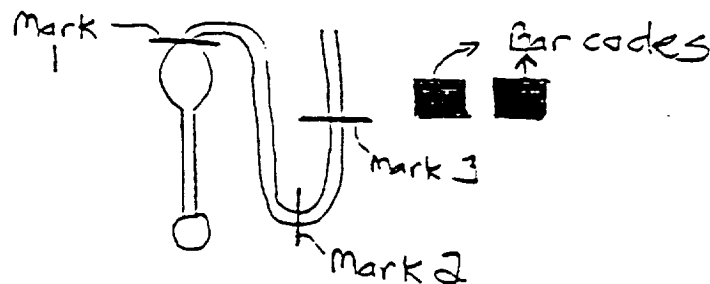
1. Place the Test Simulator cartridge into the monitor. The "PLEASE WAIT" message will appear. When answer appears, read and record result (appr. 32 sec). This ensures that the monitor is operating properly.
2. Remove a PT test cartridge from its foil wrapper, place the foil wrapper in the waste container, place the PT test cartridge in the monitor, and allow it to warm (45 sec).
3. Place a fresh lancet on the autolancet. Remove the lancet cover. Swab the fingertip with an alcohol wipe, dry with a piece of gauze, and

perform fingerstick. Recap the lancet, place alcohol wipe and used lancet in the biohazard container. Collect a drop of blood with a 50 microliter capillary tube.

4. When the analyzer states "APPLY DROP OF BLOOD", apply a drop of blood from the capillary tube onto the sample well (the "APPLY DROP OF BLOOD" message stays lit for 90 seconds, then the message disappears and the test cartridge must be reinserted if the drop of blood has not been applied). Apply pressure to the finger with the piece of gauze. Discard gauze in the biohazard container when finished.
5. The test result will be displayed in approximately 30 seconds. Read and record result.
6. Remove cartridge from monitor, mark a line with a permanent marker where the cessation of blood flow occurred, the name of the subject, and date, and place in a container for biohazardous materials. These cartridges will be kept for future analysis (visual observation of capillary channels).

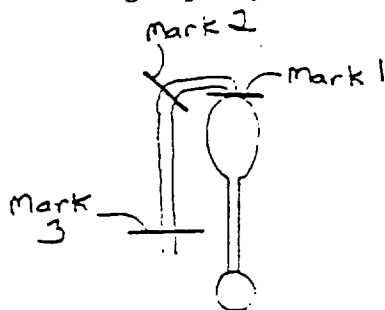
Study 2: Flow vs. Time

PT Cartridge capillary channel marks:



mark 3 is placed adjacent to the bottom of the bar codes on the cartridge

PTT Cartridge capillary channel marks:



Mark 3 is placed at the bottom of the inside of the black fluid barrier on the cartridge

1. Remove a PT or PTT cartridge from its foil wrapper. Label the appropriate places with a permanent marker.
2. Perform fingerstick as described above and apply blood to cartridge. Simultaneously start the stopwatch and record the times at which the blood crosses the marks on the cartridge.
3. Place the cartridge into its foil wrapper and discard into a biohazardous container.
4. Repeat steps 1-3 until a minimum of 10 results are obtained on each cartridge.

IN-FLIGHT PROCEDURES

0-G Testing of the Ciba-Corning 512 Coagulation Monitor:

A lap board that can be securely fastened to the arm rests of two chairs will be used. The board has strips of velcro that can be placed around the bottom of the arm rests and be brought around to the top of the board, securely fastening it to the chairs. Supplies will be contained in a box which is velcroed to the lap board. The monitor will be velcroed to the lap board as well as a biohazard container. The board will necessitate the placement of the subjects in three seats because the board straps onto two seats and half of another seat. It will be necessary to be seated in the front row.

Study 1

1. The first 2 parabolas are on a contingency basis.
2. During 0-g of the 3th parabola, place the Test Simulator cartridge into the monitor. The "PLEASE WAIT" message will appear. When the answer appears, read and record result (appr. 32 sec). This ensures that the monitor is operating properly.
3. During 0-g of the 4th parabola remove a PT test cartridge from its foil wrapper (store the foil wrapper to place used cartridge into), place the PT test cartridge in the monitor, and allow it to warm (45 sec).
4. Place a fresh lancet on the autolancet. Uncap the lancet. Swab the finger with an alcohol wipe, dry with a piece of gauze, and perform fingerstick. Recap the lancet, place alcohol wipe and used lancet in the biohazard container. Collect a drop of blood in a 50 microliter capillary tube.
5. During 0-g of the 5th parabola, when the analyzer states "APPLY DROP OF BLOOD", apply a drop of blood from the capillary tube onto the sample well (the "APPLY DROP OF BLOOD" message stays lit for 90 seconds, then the message disappears and the test cartridge must be reinserted if the drop of blood has not been applied). Apply pressure to the finger with the piece of gauze. Place the gauze in the biohazard container when finished.
6. The test result will be displayed in approximately 30 seconds. Read and record result.
7. Remove cartridge from monitor, mark a line with a permanent marker where the cessation of blood flow occurred, name of subject, and date. Place into its foil wrapper and discard into a container for biohazardous materials. These cartridges will be kept for future analysis (visual observation of capillary channels).
8. The PT test will only be able to be performed every other parabola due to the warm-up time of the cartridge (45 sec). Study #1 will be performed during the odd numbered parabolas beginning with parabola 5 and Study #2 will be performed during the even numbered parabolas beginning with parabola 4.

STUDY #2 (Flow vs time):

First set of 10 parabolas:

1. During the time it takes for the KC-135 to reach the point where it begins parabolas, remove 5 PT cartridges from their respective foil wrappers. Place velcro strips on the bottom of each cartridge and mark the appropriate places for timed studies with a permanent marker. Place cartridges under the velcro straps on the lap board.
2. The first 2 parabolas are on a contingency basis.
3. Perform a fingerstick as described above (in the 2-g portion of the latter part of the 3rd parabola). In 0-g of the 4th parabola, place a drop of blood from the capillary tube onto the sample well of the cartridge. Simultaneously start the stopwatch.
4. Record the time that it takes for the blood to reach each point marked on the cartridge.
5. Perform this study in the 0-g portions of the even numbered parabolas.

Second set of 10 parabolas:

6. When the first set of 10 parabolas is completed and the KC-135 is in a go-around, unwrap 5 more PT cartridges, place velcro strips on back of them, and mark the appropriate places for timed studies. Place cartridges under the velcro straps on the lap board.
7. Perform steps 3 and 4 above beginning with 0-g of the 12th parabola.

Third set of 10 parabolas:

8. When the second set of 10 parabolas is completed and the KC-135 is in a go-around, unwrap 5 more PT cartridges, place velcro strips on back of them, and mark the appropriate places for timed studies. Place cartridges under the velcro straps on the lap board.
9. Perform steps 3 and 4 above beginning with 0-g of the 22nd parabola.
10. When the third set of 10 parabolas is completed and the KC-135 is in a go-around, unwrap 5 PTT cartridges, place velcro strips on back of

them, and mark the appropriate places for timed studies. Place cartridges under the velcro straps on the lap board.

11. Perform steps 3 and 4 above beginning with 0-g of the 32nd parabola.

POST-FLIGHT PROCEDURES

1-G Testing of the Ciba-Corning 512 Coagulation Monitor:

Study #1:

1. Place the Test Simulator cartridge into the monitor. The "PLEASE WAIT" message will appear. When answer appears, read and record result (appr. 32 sec). This ensures that the monitor is operating properly (this procedure should be performed daily).
2. Remove a PT test cartridge from its foil wrapper (save the foil wrapper to place used cartridge into), place the PT test cartridge in the monitor, and allow it to warm (45 sec).
3. Place a fresh lancet on the autolancet. Uncap the lancet. Swab the finger with an alcohol wipe, dry with a piece of gauze, and perform fingerstick. Collect a drop of blood in a 50 microliter capillary tube. Recap the lancet, place alcohol wipe and used lancet in the biohazard container.
4. When the analyzer states "APPLY DROP OF BLOOD", apply a drop of blood from the capillary tube onto the sample well (the "APPLY DROP OF BLOOD" message stays lit for 90 seconds, then the message disappears and the test cartridge must be reinserted if the drop of blood has not been applied). Apply pressure to the finger with the piece of gauze. Discard the gauze in the biohazard container when finished.
5. The test result will be displayed in approximately 30 seconds. Read and record result.
6. Remove cartridge from monitor, mark a line with a permanent marker where the cessation of blood flow occurred, name of subject, and date, and place into its foil wrapper, and place in a container for biohazardous materials. These cartridges will be kept for future analysis (visual observation of capillary channels).

STUDY #2 (Flow vs time):

1. Remove a PT or PTT cartridge from its foil wrapper. Label the appropriate places with a permanent marker.
2. Perform fingerstick as described above and apply blood to cartridge. Simultaneously start the stopwatch and record the times at which the blood crosses the marks on the cartridge.
3. Place the cartridge into its foil wrapper and discard into a biohazardous container.
4. Repeat steps 1-3 until a minimum of 10 results are obtained on each cartridge.

DISCUSSION:

Observations and comments from Flight Investigators:

All blood during the KC-135 flight was introduced to the sample well with a glass capillary tube by means of a plunger within the capillary tube. Glass is known to adhere platelets which interferes with PT and PTT readings, although the time that the blood was in the capillary tube did not seem to affect the results of the PT tests performed.

The fingerstick was performed in the 2-g portion of the parabola, therefore the blood crept down the finger causing the collection of the sample to be difficult. Tissue fluids, epithelial cells and other contaminants may have been introduced into the sample by scraping the skin when collecting the sample. The results seem very reasonable considering these problems.

All flight subjects were medicated with Scopalamine during the flight. It is unknown whether or not this affected the PT results. It would be helpful to obtain results with the subjects medicated in one-g.

Results:

The results for the study are arranged in a matrix (see Appendix A) with appropriate comments after each entry. Close attention should be paid to these comments due to errors that may have occurred in sampling, pipetting, etc. PT Level I control was consistently out of range due to problems with

the control itself. When a new lot was purchased, no problems evolved.

Test simulator results were excellent pre- and post-flight (32 sec consistently); in-flight results were not obtained due to the warm-up time required for the simulator. Since this is an electronic function only, the expected results on the simulator would be the same in zero-g.

The following table contains each subject number, number of samples obtained, mean, one standard deviation, and accuracy (5% is the accepted accuracy in ground-based clinical laboratories). Position 3 of the flow vs time study was not studied in-flight due to amount of time that it took for the blood to reach the position (~23-27 sec). No results were obtained post-flight in any position for the flow vs time study.

OPERATION AND PERFORMANCE OF THE CIBA-CORNING 512 COAGULATION
MONITOR DURING PARABOLIC FLIGHT

TABLE 1

<u>SUBJECT</u>	<u>#SAMPLES</u>	<u>MEAN</u> <u>(sec)</u>	<u>ONE STD DEV</u>	<u>ACCURACY</u> <u>(%)</u>
<i>Pre-flight:</i>				
#1	12	11.1	0.49	~4.5
#2	1	10.7		
#3	1	10.5		
#4	3	11.0	0.44	4.0
<i>In-flight:</i>				
#1	1	10.7		
#2	8	11.2	0.67	6.0
#3	0			
#4	0			
<i>Post-flight:</i>				
#1	0			
#2	4	11.0	0.68	~6.0
#3	0			
#4	0			
<i>Flow vs Time</i>				
<i>Pre-flight:</i>				
Position 1	4	9.5	1.9	20
2	7	15.6	1.6	10
3	7	24.7	1.8	7
<i>In-flight:</i>				
Position 1	13	11.6	1.6	14
2	5	21.2	1.5	7
3		0		

SUMMARY:

The accuracy readings for the test results obtained (see Table 1 above) were satisfactory with the exception of the flow vs time study (Study #2). This study need further investigation to determine if flow is consistent in a zero-gravity environment.

The Ciba-Corning 512 Coagulation Monitor is best suited for the Space Station due to the use of whole blood, dry reagents, and capillary action (closed system). Minimal modifications would be needed for zero-g adaptibility. The monitor produced acceptable accuracy (flow vs time study needs further investigation) and a complete evaluation should be performed in a one-g environment.

At the present time, Biotrack, Inc. (manufacturer of the 512) is not interested in participating in the conversion into flight hardware.

HAZARD ANALYSIS COVER SHEET

DATE:	February 26, 1990
HAZARD ANALYSIS OF:	Ciba-Corning 512 Coagulation Monitor
SYSTEM/BUILDING NUMBER:	Parsec II (KRUG - HMF)
SYSTEM/BUILDING NAME:	Parsec II (KRUG - HMF)
PREPARED BY:	Robyn Gocke
ORGANIZATION (MAIL CODE):	MDSSC - CHcCS
TELEPHONE EXTENSION:	283-4832

HAZARD ANALYSIS REPORT

SYSTEM PURPOSE:

The Ciba-Corning 512 Coagulation Monitor represents an analyzer for the Medical Analytical Laboratory subsystem of the Health Maintenance Facility.

Its size, weight, volume, and whole blood capability allow for a more effective method of performing blood coagulation analyses.

SYSTEM FUNCTIONAL DESCRIPTION:

The Ciba-Corning 512 Coagulation Monitor is a hand-held laser photometer weighing 1.2 lb. The blood sample travels through the cartridge capillary channel and the built-in laser detects the cessation of blood flow (clotting) by sensing variation in the movement of red blood cells. The time elapsed between sample application and clotting is automatically measured. The PT result is displayed in seconds as a ratio to normal.

HAZARD ANALYSIS SUMMARY:

1. Blood loss from the PT test cartridge

If a small amount of blood leaks or floats out of the test cartridge, the other investigators will be prepared to clean it up with towels. Large fluid loss is not anticipated since the system will be checked out in the laboratory prior to the flight.

2. Waste containment

All waste will be placed in a container for biohazardous material. The container will be velcroed to the lap board which will be strapped to two flight seats.

3. Fingersticks

All fingersticks will be self-sticks. A secondary person will supervise the stick in case problems arise such as prolonged bleeding or loss of lancet to environment. Extra gauze pads and alcohol swabs will be available. The secondary person will be prepared to perform the fingerstick if necessary.

4. Gloves

Latex gloves will be available in the event that the subject cannot perform a satisfactory fingerstick on him/herself. The person performing the fingerstick will put on gloves before performing the stick.

NASA PHOTO REFERENCE

S90-31852 - 54

Sample preparation

S90-31859 - 60

Sample acquisition (thumb stick)

S90-31865

Sample testing

OPERATION AND PERFORMANCE OF THE CIBA-CORNING 512 COAGULATION
MONITOR DURING PARABOLIC FLIGHT

	A	B DATE	C TEST SIMULATOR sec (flange: 31-33 sec)	D PT sec	E APIT sec	F R VALUE	G INIT VALUE	H SUBJECT	I FLOW VS TIME STUDY		K POSITION 3 sec
									POSITION 1 sec	POSITION 2 sec	
1											
2											
3											
4											
5	Lot numbers of cartridges										
6	and controls used (see remarks)										
7											
8	PNE-FLIGHT RESULTS										
9		11/8/89	32			1.00					
10		11/9/89	32	11.9		0.99	0.90	Subject #1			
11		11/9/89	32			1.00		Subject #1			
12		11/13/89	32					Subject #1			
13	Data not used in evaluation	11/13/89						Subject #1			
14		11/13/89	32	11		0.92	0.84	Subject #1			
15		11/15/89	32			1.00		Subject #1			
16		11/15/89		11.3		0.94	0.88	Subject #1			
17		11/15/89		10.2		0.85	0.71	Level 1			
18		11/15/89	32	22		1.84	3.46	Level 2			
19		11/17/89				1.00		Level 1			
20		11/17/89		10.2		0.85	0.71	Level 1			
21		11/17/89		23.7		1.98	4.02	Level 2			
22		11/17/89		10.9		0.91	0.83	Subject #1			
23		11/17/89		11.3		0.94	0.88	Subject #1			
24		2/1/90	32			1.00		Subject #1			
25		2/1/90		11.4		0.95	0.9	Subject #1			
26		2/1/90		9.2		0.77	0.59	Level 1			
27		2/1/90		21.3		1.77	3.21	Level 2			
28		2/8/90	32			1.00		Subject #1			
29		2/8/90		11.1		0.92	0.85	Subject #1			
30		2/8/90		10.7		0.89	0.78	Subject #2			
31		2/8/90		10.5		0.87	0.75	Subject #3			
32		2/12/90	32			1.00		Level 1			
33		2/12/90		9.4		0.78	0.61	Level 2			
34		2/12/90		24.7		2.06	4.35	Subject #1			
35		2/12/90		10.4				Subject #1			
36	Data not used in evaluation	2/12/90		10.2		0.85	0.71	Subject #1			
37		2/12/90							17	29	
38		2/12/90							21	32	
39		2/12/90							17	25	
40		2/12/90									
41		2/13/90	32			1.00		Subject #1			
42		2/13/90		11.6		0.97	0.93	Subject #1			
43		2/13/90		10.1		0.94	0.71	Subject #1			
44		2/13/90						Subject #1	18	29	
45		2/13/90		9.8				Subject #1	16	29	
46	Data not used in evaluation	2/13/90		9.9				Subject #1			
47	Data not used in evaluation	2/13/90	32			1.00		Subject #1			
48		2/15/90				0.94	0.88	Subject #1			
49		2/15/90		11.2		0.93	0.86	Subject #1			
50		2/15/90		10.8		0.9	0.8	Subject #4			
51		2/15/90		10.7		0.89	0.79	Subject #4			
52		2/15/90		11.5		0.98	0.91	Subject #4			
53		2/15/90							15	23	
54		2/15/90							17	27	
55		2/15/90							17	27	
56		2/15/90							17	25	
57		2/15/90							16	23	
58		2/15/90							10	23	
59		2/20/90							12	23	
60		2/20/90									

OPERATION AND PERFORMANCE OF THE CIBA-CORNING 512 COAGULATION
MONITOR DURING PARABOLIC FLIGHT

A	B	C	D	E	F	G	H	I	J	K
	DATE	TEST SIMULATOR	PT	APT	R VALUE	INIT VALUE	SUBJECT	POSITION 1	POSITION 2	POSITION 3
		(Range: 31-33 sec)	sec	sec				sec	sec	sec
1										
2										
3										
61	2/20/90	32	9.5		1.03		Level 1			
62	2/20/90		22.3		0.79	0.62	Level 2			
63	2/20/90				1.06	0.95	Level 1			
64	2/20/90		12.1		1.01	1.01	Level 1			
65	2/20/90		33.9		2.83	8.32	Level 2			
66	2/20/90			58.9	1.9		Level 1			
67	2/20/90			105.5	3.4		Level 2			
68										
69	IN-FLIGHT RESULTS									
70	PARABOLA									
71	1									
72	2									
73	3									
74	4									
75	5									
76	6		10.7		0.69	0.79	Subject #1			
77	7									
78	8							13		
79	9									
80	10									
81	11		10.2		0.65	0.71	Subject #2			
82	12		11.2		0.95	0.91	Subject #2	10	22	
83	13							11		
84	14									
85	15		11.3		0.94	0.99	Subject #2	12		
86	16									
87	17									
88	18									
89	19		11.3		0.94	0.98	Subject #2			
90	20									
91	21									
92	22		10.1		0.84	0.7	Subject #2	12		
93	23									
94	24		11.9		0.99	0.98	Subject #2	10	21	
95	25									
96	26		11.5		0.96	0.92	Subject #2	13		
97	27									
98	28		11.8		0.98	0.96	Subject #2	10	21	
99	29									
100	30 - Data not used in evaluation		12.2		1.01	1.03	Subject #2	14		
101										
102										
103										
104										
105										
106										
107	POST-FLIGHT RESULTS									
108										
109	3/20/90	32	10.3		1.03		Subject #2	14		
110	3/20/90		10.8		0.85	0.73	Subject #2			
111	3/20/90		12		0.86	0.77	Subject #2	11	23	
112	3/28/90		11.3		1	1	Subject #2	12		
113	3/28/90		11.8		0.94	0.88	Subject #2	9	19	
114	3/28/90	32			0.96	0.96	Subject #2			

OPERATION AND PERFORMANCE OF THE CIBA-CORNING 512 COAGULATION
MONITOR DURING PARABOLIC FLIGHT

L	
1	REMARKS
2	
3	
4	
5	Cartridges: PT-P802H36, P80218; PTT- CA9J12 Controls: PT-CP9E05,CP9K15; PTT-CA9J12
6	
7	
8	
9	
10	
11	
12	
13	Insufficient drop of blood
14	
15	
16	
17	Lot CP9E05 (range: 10.3-12.7), exp. 8/91. Level 1 out of range. Improper dilution is possible due to pipet.
18	Lot CP9E05 (range: 21.1-27.1), exp 8/91.
19	
20	Lot CP9E05 (range: 10.3-12.7), exp. 8/91. Level 1 out of range. Improper dilution is possible due to pipet.
21	Lot CP9E05 (range: 21.1-27.1), exp 8/91.
22	Drawn in AM
23	Drawn in PM
24	
25	
26	Lot CP9E05 (range: 10.3-12.7), exp. 8/91. Level 1 out of range. Improper dilution is possible due to pipet.
27	Lot CP9E05 (range: 21.1-27.1), exp 8/91.
28	
29	
30	
31	
32	
33	Lot CP9E05 (range: 10.3-12.7), exp. 8/91. Level 1 out of range. Improper dilution is possible due to pipet.
34	Lot CP9E05 (range: 21.1-27.1), exp 8/91.
35	
36	Repeat on same stick
37	Heparinized blood-didn't clot, Interrupted test
38	Test to time flow in cartridge (unheated flow study), injected in center of sample well, heparinized blood.
39	EDTA blood, injected in back of sample well
40	Sodium citrated blood, injected in center of sample well
41	
42	Blood introduced with finger
43	Blood introduced with capillary tube
44	
45	
46	After using same fingerstick 3 times
47	After using same fingerstick, squirted due to clot
48	
49	Blood introduced with finger, total time from sample introduction to result-31 sec
50	Blood introduced with capillary tube, total time from sample introduction to result-31 sec
51	Blood introduced with finger, total time from sample introduction to result-31 sec
52	Blood introduced with capillary tube, total time from sample introduction to result-31 sec
53	Blood introduced with capillary tube, total time from sample introduction to result-31 sec
54	EDTA blood
55	EDTA blood
56	EDTA blood
57	EDTA blood
58	EDTA blood
59	EDTA blood
60	EDTA blood

OPERATION AND PERFORMANCE OF THE CIBA-CORNING 512 COAGULATION
MONITOR DURING PARABOLIC FLIGHT

1	L
2	REMARKS
3	
61	
62	Lot CP9E05 (range: 10.3-12.7), exp. 8/91. Level 1 out of range.
63	Lot CP9E05 (range: 21.1-27.1), exp. 8/91.
64	Lot CP9K15 (range: 10.7-13.1), exp. 8/91
65	Lot CP9K15 (range: 18.1-23.3), exp. 8/91
66	Lot CA9J12 (range: 44.2-71.8), exp. 7/90
67	Lot CA9J12 (range: 84.7-117.1), exp. 7/90
68	
69	Everyone was medicated with Scopolamine, all blood was applied with a glass capillary tube
70	
71	Evaluation of set-up and orientation of flyers
72	Evaluation of set-up and orientation of flyers
73	Loss of parabola due to lack of time to warm test simulator
74	Pressure difference in pipette tip caused loss of blood for unheated flow study
75	
76	?clot in capillary tube, slow fill
77	Subject #1 became ill
78	
79	Missed sequence on meter - had to reinsert cartridge
80	
81	
82	
83	
84	Bad stick
85	
86	
87	Miss
88	Miss
89	
90	Miss
91	
92	
93	Very good flow study
94	
95	Started early
96	
97	Good
98	
99	Good
100	Surface tension made it hard to get blood
101	
102	Subject #3 became ill
103	Negative-g attend. Right on edge of 0-g and 2-g.
104	Late start, uneven fill
105	
106	
107	Noone was medicated
108	
109	Glass capillary tube was used for collection
110	Glass capillary tube was used for collection
111	Glass capillary tube was used for collection, blood was very slow coming out of finger (not used)
112	Glass capillary tube was used for collection
113	Blood was applied with finger (hanging drop of blood)
114	